IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF PRETRIAL ORDER NO. 9158

Bartle, J. October 30, 2013

Greta Zink ("Ms. Zink" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits") and, if so, whether she has met her burden of proving that her claim was not based, in whole or in part, on any intentional material misrepresentation of fact.[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney completes Part III if claimant is represented.

In July, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, W. Marcus Brann, M.D., F.A.C.C., F.A.C.P. Dr. Brann is no stranger to this litigation. According to the Trust, he has signed at least 765 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated April 3, 2002, Dr. Brann attested in Part II of claimant's Green Form that Ms. Zink

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2. (...continued)
for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%.[3] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $578,687.[4]

In the report of claimant's echocardiogram, the reviewing cardiologist, Alan A. Gabster, M.D., noted that Ms. Zink had moderate mitral regurgitation, which he measured to be 23%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. In addition, Dr. Gabster measured Ms. Zink's left atrial antero-posterior dimension as 4.1 cm, but he did not measure her left atrial supero-interior dimension. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long-axis view or a left atrial supero-inferior systolic dimension greater than

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3. Dr. Brann also attested that claimant suffered from moderate aortic regurgitation and New York Heart Association Functional Class II symptoms. These conditions are not at issue in this claim.

4. Under the Settlement Agreement, an eligible class member is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). An abnormal left atrial dimension and a reduced ejection fraction are each one of the complicating factors needed to qualify for a Level II claim.

5.3 cm in the apical four chamber view. See id. at § IV.B.2.c.(2)(b). Dr. Gabster also attested that claimant had an ejection fraction of 68%. Under the Settlement Agreement, an ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See Settlement Agreement § IV.B.2.c.(2)(b)iv).

In December, 2003, the Trust forwarded the claim for review by Martin S. Kanovsky, M.D., F.A.C.C., F.A.C.P., one of its auditing cardiologists. In audit, Dr. Kanovsky concluded that there was a reasonable medical basis for Dr. Brann's Green Form representations.

Based on Dr. Kanovsky's findings, the Trust issued a post-audit determination awarding Ms. Zink Matrix Benefits. Before the Trust paid Ms. Zink's claim, we imposed a stay on the processing of claims pending implementation of the Seventh Amendment to the Settlement Agreement. See Pretrial Order ("PTO") No. 3511 (May 10, 2004). Prior to entry of the stay, the Trust identified 968 Matrix claims that had passed audit as payable, which were designated as "Pre-Stay Payable Post-Audit Determination Letter ('PADL') Claims." Pursuant to Paragraph 5 of PTO No. 3883, the Trust was ordered to separate the Pre-Stay Payable PADL Claims into three categories. Of the 968 Pre-Stay Payable PADL Claims, the Trust alleged that 580 claims, including Ms. Zink's, contained intentional material misrepresentations of fact. These 580 claims are commonly referred to as "5(a) claims." See PTO No. 3883 at ¶ 5 (Aug. 26, 2004).

Following the end of the stay, we ordered the Trust to review the 580 claims designated as 5(a) claims and issue new post-audit determinations, which claimants could contest. See PTO No. 5625 (Aug. 24, 2005). Prior to the Trust's review of Ms. Zink's claim, on November 22, 2006, this court approved Court Approved Procedure ("CAP") No. 13, which provided 5(a) claimants with the option either to submit their claims to a binding medical review by a participating physician or to opt-out of CAP No. 13. See PTO No. 6707 (Nov. 22, 2006). Ms. Zink elected to opt-out of CAP No. 13.

The Trust therefore undertook to determine whether there were any intentional material misrepresentations of fact made in connection with Ms. Zink's claim. As part of this review, the Trust engaged Joseph Kisslo, M.D., to review the integrity of the echocardiogram system used during the performance of the echocardiographic study and the resulting interpretation submitted in support of Ms. Zink's claim. As stated in his February 8, 2007 declaration, Dr. Kisslo determined, in pertinent part, that:

> 53. ***Measurement Exaggerations:*** Beyond these setting manipulations, Echo Express selected, traced, and measured a supposed regurgitant "jet" that consists of backflow, entrainment, and areas outside of the jet boundary rather than true high velocity sustained regurgitant flow as required by the Settlement Agreement. The purported regurgitant jet area(s) ("RJA") that are planimetered on this study misrepresent the true extent of Claimant's mitral regurgitation. This mismeasurement artificially inflates the RJA/LAA ratio.

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> 59. ***Exaggeration of Jet and Complicating Factor:*** In Ms. Zink's study, the use of high color gain, high image gain, decreased Nyquist and color pixel dominance[,] the selection and planimetry of backflow, and the overmeasurement of the mitral "jet," as well as the overmeasurement of the left atrial dimension are the result of deliberate choices and conduct engaged in by the sonographer performing this study and at a minimum, acquiesced in by the Attesting Physician. Each of these manipulations exaggerated or created the appearance of regurgitation, jet duration or a complicating factor. There is no responsible physiologic or hemodynamic construct under which this echocardiogram can be assessed as demonstrating moderate mitral regurgitation. Ms. Zink has only mild mitral regurgitation--not moderate mitral regurgitation as claimed by the Attesting Physician. There is no reasonable medical basis for a finding of moderate mitral regurgitation based on this study.

Thus, notwithstanding Dr. Kanovsky's findings at audit, the Trust rescinded its prior post-audit determination letter and issued a new post-audit determination denying Ms. Zink's claim based on its conclusion that there was substantial evidence of intentional material misrepresentations of fact in connection with the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), Ms. Zink contested this adverse determination.[5] In contest, Ms. Zink argued that the

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5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit (continued...)

results of Dr. Kanovsky's audit, who claimant says is "the only impartial unbiased cardiologist to review this echocardiogram tape (besides Ms. Zink's attesting cardiologist)," support her claim. Ms. Zink also attached a September 8, 2005 letter from Class Counsel to the Trust[6] and a motion filed on behalf of a number of other claimants to enforce PTO No. 5632 or to set aside PTO No. 5632 and to compel production of certain Trust documents,[7] each of which she contended established that Dr. Kisslo was neither credible nor reliable. In addition, Ms. Zink argued that the Trust failed to meet the legal requirements for a claim of intentional material misrepresentations of fact. Finally, claimant submitted an

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5. (...continued)
Rules contained in PTO No. 2807 apply to Ms. Zink's claim.

6. In this letter, Class Counsel argued, among other things, that the Trust could not deny payment on any claim in which a post-audit determination letter had been sent unless it found that the claim was based on a fraudulent echocardiogram and that the Trust could not rely on the reports of Dr. Kisslo to determine whether a claim in which a post-audit determination letter had been sent was fraudulent. The issues raised in Class Counsel's letter also were the subject of a motion filed by Class Counsel and joined by a number of firms representing various Class Members. Class Counsel and all but one firm subsequently withdrew the motion after the adoption of certain Court Approved Procedures. We denied the motion of the remaining firm following briefing and argument. See PTO No. 6099 (Mar. 31, 2006).

7. We subsequently denied the motion. See Mem. in Supp. of PTO No. 9114 at 6 n.8 (July 23, 2013).

expert report of Dr. Brann,[8] wherein he states, in pertinent part, that:

> 1. [Dr. Kisslo's] Declaration is just a template in which he filled in names and a few numbers relevant to the study at hand. Otherwise, all of his declarations read verbatim exactly the same. This tells me that he attempting [sic] to show guilt by association, that all of Echo Express's studies are suspect, regardless of the facts of the individual study.
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> 2. Dr. Kisslo has attempted to disqualify all of Echo Express' studies by generating his own data from elaborate echocardiography experiments on volunteer subjects to demonstrate how echocardiography equipment settings could have been manipulated. I found his treatise to be interesting reading but these experiments in no way prove that the same manipulations were performed during Ms. Hernandez's study and that Echo Express generated erroneous results....
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> 3. Dr. Kisslo asserts in each Declaration that Nyquist levels were inappropriately set. He makes the exact same statement in all of his Declarations I reviewed....
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> ....
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> 5. A good [echocardiogram] technician will adjust [echocardiogram] settings on a regular basis in order to provide the best quality images for interpretation. This is not manipulation; the technology is powerful and allows the technician to adjust the settings for the best quality images for each patient since each patient is different. No one setting applies to every patient. At the

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8. Dr. Brann's report does not appear specific to Ms. Zink as it refers to a "Ms. Hernandez."

> University of Utah, we train students to be echocardiography technicians and we train them to adjust the settings for each patient as needed and I suspect Dr. Kisslo does the same at his institution. This is why his echocardiogram experiments on test subjects do not prove a pattern of abuse. His experiments do prove, though, that settings must be adjusted for each patient....
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> 6. Whatever imaging settings are used, the reading physician is the final arbiter of the quality of the study. I have read a number of studies performed by Echo Express and I did not always agree with the technician's measurement of the mitral or aortic regurgitant jets. I re-measured jets myself when appropriate.
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> 7. I have reviewed fen-phen echocardiogram reports where I did not agree with the physician's interpretation of the severity of the valvular regurgitation. It is important to be critical of the technician's measurements and I found that not all physician readers exert such care. In some of the studies I reviewed that Dr. Kisslo also reviewed, I came to similar conclusions that the regurgitant jets were not accurately measured. But I do not agree that these studies are fraudulent or inaccurate due to manipulation of settings. Instead, the technicians simply did not measure the jets accurately and the reading physician did not question or redo the measurements.[9]

The Trust then issued a final post-audit determination, again denying Ms. Zink's claim. The Trust argued that Dr. Kanovsky's audit results do not support her claim because

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9. Dr. Brann also opined that ingestion of Diet Drugs causes VHD.

Dr. Kanovsky, unlike the Consensus Expert Panel, was not trained to detect the manipulations used by claimant's sonographer. The Trust also asserted that Dr. Brann's report fails to provide a reasonable medical basis to support the claim, because his "criticisms of Dr. Kisslo's Echo Express studies are entirely general in nature," "[h]e never disputes the specific findings made by Dr. Kisslo regarding [her] echocardiogram and the mismeasurements and setting manipulations identified therein," and "[h]e makes no reference whatever to [claimant's] study."

Ms. Zink disputed this final determination and requested that her claim proceed through the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Zink's claim should be paid. On July 26, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7332 (July 26, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master, relying upon the materials she submitted in contest. On September 24, 2007, the Trust informed the Special Master that it would not submit a reply. Under the Audit Rules, it is within

the Special Master's discretion to appoint a Technical Advisor[10] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's findings.[11] Where the Trust's post-audit determination finds intentional material misrepresentations of fact, the claimant has the burden of proving that all representations of material fact in connection with her claim are true. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form either because of

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10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

11. Given our resolution with respect to whether there is a reasonable medical basis for the attesting physician's finding that Ms. Zink suffered from moderate mitral regurgitation, we need not determine whether there is a reasonable medical basis for finding that she suffered from an abnormal left atrial dimension or a reduced ejection fraction.

an intentional material misrepresentation of fact or some other valid reason, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers with no intentional material misrepresentations of fact made in connection with the claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that it was not conducted in a manner consistent with medical standards. Specifically, Dr. Vigilante observed:

> All of the usual echocardiographic views were obtained. However, the images were not conducted in a manner consistent with medical standards. There was excessive image gain with "sparkling" of the myocardium in all views. In addition, there was excessive color gain causing color artifact seen within the myocardial tissue and even outside of the heart. In addition, persistence with "stuttering" cardiac images was noted with systolic color images seen during diastolic echo images. The Nyquist limit was set too low at 51 cm per second at a depth of 13.5 cm in the parasternal long axis view as well as a Nyquist limit of 51 cm per second at a depth of 16.2 cm in the apical two chamber and apical four chamber views. There was no apparent imaging issue that would cause the sonographer to use such a low Nyquist limit during the color flow study. In addition, low velocity, non-mitral regurgitation flow was measured as part of the RJA by the sonographer on the study.

Despite these deficiencies, Dr. Vigilante noted that he was able to evaluate claimant's echocardiogram and he determined that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation.[12] Dr. Vigilante stated, in pertinent part, that:

> A thin and central mitral regurgitation jet that did not reach the mid portion of the left atrium was noted on Doppler evaluation in the parasternal long axis view. I digitized the cardiac cycles in the apical two chamber and apical four chamber views. In spite of excessive color artifact and inappropriate demonstration of low velocity and non-mitral regurgitation flow and an inappropriately low Nyquist limit during the evaluation of the mitral regurgitation in the apical views, I was able to accurately planimeter the RJA in the mid portion of systole. The largest RJA was 1.6 cm2 in the apical two chamber view. The largest RJA was 1.5 cm2 in the apical four chamber view. I was able to accurately determine the LAA in this study. The LAA was 16.9 cm2. Therefore, the largest RJA/LAA ratio was less than 10%. The RJA/LAA ratio never came close to approaching 20%. The majority of the RJA/LAA ratios were less than 7%. There were two supposed regurgitant jet areas measured by the sonographer. The measurements were 4.03 cm2 and 4.42 cm2. These measurements were not representative of mitral regurgitation and included a great deal of low velocity and non-mitral regurgitation flow at the beginning of systole and immediately after the QRS complexes. These jets are reflections of backflow. The sonographer's measurement of the LAA of 19.32 cm2 was inaccurate as the tracing went outside the left atrium in the apical two chamber view. The correct LAA is smaller at 16.9 cm2. The inaccurate sonographer

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12. Dr. Vigilante also determined that there was no reasonable medical basis for Dr. Brann's representations that claimant had an abnormal left atrial dimension or a reduced ejection fraction.

> measurements of the RJA of 4.42 cm2 and LAA of 19.32 cm2 were the same measurements as documented by Dr. Gabster in his formal echocardiogram report.

After reviewing the entire show cause record, we find claimant has not established a reasonable medical basis for the attesting physician's finding that Ms. Zink had moderate mitral regurgitation. In reaching this determination, we are required to apply the standards delineated in the Settlement Agreement and Audit Rules. In the context of these two documents, we previously have explained that conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See Mem. in Supp. of PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

Here, Dr. Kisslo found that claimant's sonographer improperly "selected, traced and measured a supposed regurgitant 'jet' that consists of backflow, entrainment, and areas outside of the jet boundary rather than true high velocity sustained regurgitant flow." In addition, Dr. Vigilante determined that

the sonographer's measurements of claimant's supposed RJAs "were not representative of mitral regurgitation and included a great deal of low velocity and non-mitral regurgitation flow at the beginning of systole and immediately after the QRS complexes" and that the sonographer's LAA measurement "was inaccurate as the tracing went outside the left atrium in the apical two chamber view." Dr. Vigilante noted that these inaccurate measurements were the same ones documented in Dr. Gabster's echocardiogram report. Finally, Dr. Kisslo and Dr. Vigilante found that the echocardiogram of attestation was not conducted in a manner consistent with medical standards because, among other things, the echocardiogram settings included clear evidence of a decreased Nyquist setting, high image gain, and high color gain. These characteristics distort the supposed regurgitant "jet" in claimant's echocardiogram.

Notwithstanding these deficiencies, Dr. Kisslo and Dr. Vigilante determined that claimant's echocardiogram demonstrated mild mitral regurgitation. In addition, Dr. Vigilante concluded, after a thorough review, that there was no reasonable medical basis for the attesting physician's representation that Ms. Zink had moderate mitral regurgitation.[13] Specifically, Dr. Vigilante explained that "the largest RJA/LAA ratio was less than 10%" and that "[t]he majority of the RJA/LAA ratios were less than 7%."

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13. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

Claimant's substantive challenge is based almost exclusively on Dr. Brann's responsive report. That report, however, fails to provide any detailed support for Ms. Zink's study. Claimant's contention that Dr. Kisslo was biased in his review is equally unavailing. Notably, Ms. Zink makes no such contention against Dr. Vigilante, an independent cardiologist appointed by the court who reached similar conclusions during a separate review. Without identifying some specific error by the Trust's expert and the Technical Advisor in connection with her claim, Ms. Zink cannot meet her burden of proof in establishing that her claim is payable.

Moreover, to the extent Ms. Zink attempts to rely on Dr. Brann's opinion that her condition was caused by her ingestion of Diet Drugs, such reliance is misplaced. Causation is not at issue in resolving this claim for Matrix Benefits. Rather, claimant is required to show that she meets the objective criteria set forth in the Settlement Agreement. As we previously concluded:

> Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred....

Mem. in Supp. of PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted that:

> ... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. The Settlement Agreement clearly and unequivocally requires that a claimant suffer from at least moderate mitral regurgitation to receive Level II benefits for a claim based on damage to the mitral valve. We must apply the Settlement Agreement as written. Accordingly, Ms. Zink's assertion that the cause of her mitral regurgitation was her ingestion of Diet Drugs is irrelevant to the issue before the court.

Finally, we reject Ms. Zink's suggestion that Dr. Kisslo's review of her claim constitutes an impermissible second audit. This argument ignores the plain language of the Audit Rules, which provides that the Trust must conduct a review separate from the auditing cardiologist with respect to whether there were any intentional material misrepresentations of fact in connection with a claim. Specifically, the Audit Rules state, in pertinent part, that:

> The Auditing Cardiologist shall review a Claim in accordance with these Rules to determine whether there was a reasonable medical basis for each answer in Part II of the GREEN Form that differs from the Auditing Cardiologist's finding on that specific issue ("GREEN Form Question at Issue"). The Trust shall review a Claim to determine whether there were any intentional material misrepresentations made in connection with the Claim. The Trust may consider information from other Claims in Audit to determine the existence of facts or a pattern of misrepresentations implicating intentional misconduct by an attorney and/or physician

> that may warrant relief pursuant to Section VI.E.8 of the Settlement Agreement.

Audit Rule 5. Based on the findings of Dr. Kisslo, the Trust denied Ms. Zink's claim, determining that the claim was based on one or more intentional material misrepresentations of fact.

Claimant disputed this determination and proceeded to the show cause process. We need not determine whether there was, in fact, any intentional material misrepresentation of fact in connection with Ms. Zink's claim given our conclusion, based on our review of the entire record, that there is no reasonable medical basis for Dr. Brann's representation that Ms. Zink had moderate mitral regurgitation.[14]

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Zink's claim for Matrix Benefits.

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14. As we previously have stated, "[s]imply because an undeserving claim has slipped through the cracks so far is no reason for this court to put its imprimatur on a procedure which may allow it to be paid." Mem. in Supp. of PTO No. 5625, at 6-7 (Aug. 24, 2005). In this same vein, we will not ignore the findings of other cardiologists simply because a claim has previously passed audit.